Center for Drug Evaluation and Research

Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) Meeting

FDA White Oak Campus, Building 31, The Great Room (Rm. 1503) White Oak Conference Center, Silver Spring, Maryland March 28 - 29, 2012

MEETING ROSTER

DESIGNATED FEDERAL OFFICER (Non-Voting)

Paul T. Tran, R.Ph

Division of Advisory Committee and Consultant Management Office of Executive Programs, CDER, FDA

ENDOCRINOLOGIC AND METABOLIC DRUGS ADVISORY COMMITTEE MEMBERS (Voting)

Erica H. Brittain, Ph.D.

Mathematical Statistician Biostatistics Research Branch National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH) Bethesda, Maryland

Eric I. Felner, M.D., MSCR Edward W. Gregg, Ph.D.

Associate Professor of Pediatrics Division of Pediatric Endocrinology Director, Pediatric Endocrinology Fellowship Program Emory University School of Medicine Atlanta, Georgia

Ellen W. Seely, M.D. Ida L. Spruill, Ph.D., R.N.

Professor of Medicine
Harvard Medical School
Director of Clinical Research
Endocrinology, Diabetes and Hypertension Division
Vice Chair for Faculty Development
Department of Medicine
Brigham & Women's Hospital
Boston, Massachusetts

Abraham Thomas, M.D., M.P.H., FACP Lamont G. Weide, M.D., Ph.D., FACE

 $\overline{(Chairperson)}$

Division Head, Endocrinology, Diabetes, Bone, and Mineral Disorders Henry Ford Hospital Whitehouse Chair of Endocrinology Detroit, Michigan Chief, Diabetes & Endocrinology

Assistant Professor, College of Nursing

Medical University of South Carolina

<u>David M. Capuzzi, M.D., Ph.D.</u> Professor of Medicine and Biochemistry

Thomas Jefferson University &

Division of Diabetes Translation

(Consumer Representative)

Charleston, South Carolina

Atlanta, Georgia

Philadelphia, Pennsylvania

Lankenau Institute for Medical Research

Chief, Epidemiology and Statistics Branch

Centers for Disease Control and Prevention (CDC)

Professor, Internal Medicine University of Missouri - Kansas City Truman Medical Centers, Diabetes Center Kansas City, Missouri

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MEETING ROSTER (cont.)

ACTING INDUSTRY REPRESENTATIVE TO THE COMMITTEE (Non-Voting)

Mads F. Rasmussen, M.D., Ph.D.

(Acting Industry Representative)

Executive Director

Diabetes - Clinical Development and Research

Clinical Development, Medical and Regulatory

Affairs

Novo Nordisk Inc.

Princeton, New Jersey

TEMPORARY MEMBERS (Voting)

John H. Alexander, M.D., M.H.S.

Associate Professor of Cardiology/Medicine

Duke Clinical Research Institute Duke University Medical Center

Durham, North Carolina

William O. Cooper, M.D., M.P.H.

Professor and Vice Chair for Faculty Affairs

Department of Pediatrics

Vanderbilt University

Nashville, Tennessee

Ed J. Hendricks, M.D.

Medical Director

Center for Weight Management

Roseville and Sacramento, California

Michael D. Jensen, M.D.

Tomas J. Watson, Jr. Professor in Honor of

Dr. Robert L. Frye

Endocrine Research Unit

Mayo Clinic

Rochester, Minnesota

Richard N. Bergman, Ph.D.

The Alfred Jay Firestein Chair in Diabetes Research Director, Cedars-Sinai Diabetes and Obesity Research

Institute

Los Angeles, California

Allison B. Goldfine, M.D.

Assistant Director of Clinical Research

Joslin Diabetes Center, Research Division

Boston, Massachusetts

William R. Hiatt, M.D., FACP

Professor of Medicine

Division of Cardiology

University of Colorado School of Medicine

President, Colorado Prevention Center (CPC) Clinical

Research

Aurora, Colorado

Sanjay Kaul, M.D.

Director, Fellowship Training Program in

Cardiovascular Diseases

Cedars-Sinai Heart Institute

Professor, David Geffen School of Medicine at UCLA

Division of Cardiology

Cedar Sinai Medical Center

Los Angeles, California

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MEETING ROSTER (cont.)

TEMPORARY MEMBERS (Voting)

Marvin A. Konstam, M.D.

Chief Physician Executive
The CardioVascular Center
Tufts Medical Center
Professor of Medicine
Tufts University School of Medicine
Boston, Massachusetts

Lynn McAfee (Patient Representative)

North Port, Florida

Peter J. Savage, M.D.

Senior Advisor to the Director Division of Diabetes, Endocrinology & Metabolic Diseases (DDEMD) National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), NIH Bethesda, Maryland

Jack A. Yanovski, M.D., Ph.D.

Chief, Section on Growth and Obesity Program in Developmental Endocrinology and Genetics (PDEGEN) Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) NIH Bethesda, Maryland

SPEAKER (Non-Voting)

William C. Knowler, M.D., Dr.PH

Chief, Diabetes Epidemiology and Clinical Research Section NIDDK, NIH Phoenix, Arizona

Judith M. Kramer, M.D., M.S.

Associate Professor of Medicine
Duke University Medical Center
Executive Director, Clinical Trials Transformation
Initiative (CTTI)
Duke Translational Medicine Institute
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Michael A. Proschan, Ph.D.

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MEETING ROSTER (cont.)

GUEST SPEAKERS (Non-Voting)

George A. Bray, M.D., MACP, MACP

Boyd Professor

Chief, Division of Clinical Obesity & Metabolism Pennington Biomedical Research Center

Louisiana State University

Baton Rouge, Louisiana

Robert H. Eckel, M.D.

Professor of Medicine

Division of Endocrinology, Metabolism and Diabetes

Division of Cardiology

Professor of Physiology and Biophysics

Charles A. Boettcher II Chair in Atherosclerosis University of Colorado Anschutz Medical Campus

Aurora, Colorado

Rena R. Wing, Ph.D.

Professor of Psychiatry & Human Behavior Warren Alpert Medical School of Brown University Director, Weight Control & Diabetes Research Center

The Miriam Hospital
Providence, Rhode Island

FDA PARTICIPANTS (Non-Voting)

Robert J. Temple, M.D.

Deputy Center Director for Clinical Science Immediate Office of the Director CDER, FDA

Mary H. Parks, M.D.

Director

Division of Metabolism and Endocrinology Products (DMEP)

ODE II, OND, CDER, FDA

Solomon Iyasu, M.D., M.P.H.

Director

Division of Epidemiology I

Office of Pharmacovigilance and Epidemiology

Office of Surveillance and Epidemiology (OSE)

CDER, FDA

Curtis J. Rosebraugh, M.D., M.P.H.

Director

Office of Drug Evaluation (ODE) II Office of New Drugs (OND), CDER, FDA

Eric C. Colman, M.D.

Deputy Director

DMEP, ODE II, OND, CDER, FDA